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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,714	12/18/2006	**Dharmaraj Ramachandra Rao**	PAC/eehc/23398US (4137-00	5756

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EXAMINER	
BROOKS, CLINTON A	
ART UNIT	**PAPER NUMBER**
1621	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,714	RAO ET AL.	
	Examiner	Art Unit	
	CLINTON BROOKS	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14,15,17-19 and 30-32* is/are pending in the application.

4a) Of the above claim(s) *2-10 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,14-15 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is **FINAL.**

Status of Claims

Claims 1-10, 14-15, 17-19, 30-32 are currently pending. Claims 2-10, 30-32 are withdrawn. Claims 1, 14-15, and 17-19 are examined herein.

Response to Applicant Arguments

In view of Applicants amendment, the 112 second paragraph rejection is withdrawn.

With respect Applicant's argument that the Office Action has not established a prima facie case of obviousness in view of the currently amended claims, the argument has been considered but is not found to be persuasive for at least the following reasons.

The claims as recited use comprising language, so the claims and the arguments are not commensurate in scope. As currently recited, the claims do not require the sertraline does not have to be present through because the comprising language of the preamble allows any number of additional steps and elements to be present.

With respect to Applicant's argument that the cited references would not have a reasonable expectation of success, this argument has been considered but is not found to be persuasive for at least the following reason. Given the comprising language of the instant claims, additional steps and elements are allowed. There is a reasonable expectation of success based on the teachings of the references of record.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1, 14-15, 17-19 stand rejected under 35 USC 103(a) as being unpatentable over United states Patent No. 6,500,987 to Schwartz et al. ("the '987 patent", this patent was cited on the IDS received December 18, 2006) in view United States Patent No. 6,517,866 to Am Ende et al. ("the '866 patent", this patent was cited on the IDS received December 18, 2006).

Please note that for the purposes of examination on the merits, the "such as" language of claim 14, and claim 15 which depends from claim 14 was not given patentable weight. Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. See MPEP 2111.04.

Further, note that the term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.);Invitrogen Corp. v. Biocrest MFg., L.P., 327 F. 3d 1364, 1368, 66 USPQ2d

1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.")

Regarding independent claims 1 and 17, the '987 patent teaches adjusting the pH of the mixture of hydrogen chloride in anhydrous form (examples 9 and 10, Table 1) and aqueous form (Table 1) to form sertaline hydrogen chloride form V. The '987 patent teaches that room temperature, 35 degrees and 60 degrees Celsius can be used when adjusting the pH (Example 8-10). Example 8 of the '987 patent teaches that "[t]he mixture was cooled to room temperature and the stirring was continued for 2 hours. The solid obtained after filtration, washing with ethanol and drying at 50 degrees was sertraline hydrochloride form V." Thus, the '987 patent teaches adjusting, cooling, isolating and drying.

In addition, the '987 patent teaches that the mandelate salt of sertraline was suspended or dissolved in ethyl acetate and was neutralized to give the free base (Example 1). Further, as discussed above the '987 patent teaches that the free base can be converted to Form V (Examples 7-10).

Further, the '987 patent teaches that the pH was adjusted by hydrogen chloride to about 0.5 at 60 degrees (Example 8, claim 11-12, 18), and a pH of 3 without heating (Example 9, claim 11).

Further, the '987 patent teaches aqueous hydrogen chloride (Table I) to form sertraline hydrochloride form V. Further, the '987 patent teaches that Table I sets forth a summary of additional experiments conducted that generally followed the procedures described above (column 12, lines 3 to 5). One of the general teachings, Example 9 used ambient temperature.

Regarding claim 19, the '987 patent teaches that the cooling is done over a 2 hour period (gradually) to room temperature (Example 8).

Further, the '987 patent is not limited to the teachings of Form V, but teaches procedures for the preparations of forms II, III, VI, VII, VII, IX, and X (abstract).

The '987 patent fails to teach suspending sertraline acetate in suitable solvents, or dissolving sertaline base in acetic acid.

Regarding claims 1, the '866 patent teaches dissolving sertraline acetate in a suitable solvent (Example 39).

Regarding claim 17, the '866 patent teaches suspending/dissolving sertraline base in acetic acid. Specifically, the '866 patent teaches in Example 37 that sertraline base was dissolved in 200 microliters of ethyl acetate and 41.2 microliters of glacial acetic acid. Acetic acid, a solvent and reactant in this example makes up 17% of the total solvent volume. Also, see example 39 where the '866 patent teaches sertraline base with 23 mL of glacial acetic acid.

Regarding claims 14 and 15, the '866 patent teaches that sertraline acetate has a water solubility of 84 mg/mL (column 51, lines 11-15). Further, the '866 patent teaches the acetate salt of sertaline is highly water soluble (column 10, lines 12 to 15). Still further, claim 14 recites "such as" language, and claim 15 depends from claim 14.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the teachings of the '987 patent with the teachings of the '866 patent. One skill in the art at the time the invention was made would be motivated to do so because sertraline acetate is an equivalent of sertraline mandelate. In this case, both forms are

known in the art. Upon treatment with a base, both sertraline mandelate and sertaline acetate would form the free base. As stated MPEP § 2144.06 it is prima facie obvious to substitute equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components. However, an applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); ** Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.). An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)

Further, one skilled in the art at the time the invention was made would be motivated to use sertraline acetate over sertaline mandelate because using acetic acid to form the acetate salt would reduce the cost of the process.

One would expect success in the combination because both salts, the acetate and mandelate, give the same product, sertraline free base, which the '798 patent teaches can form sertraline Form V.

Conclusions

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON BROOKS whose telephone number is (571)270-7682. The examiner can normally be reached on Monday-Friday 8:00 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, DANIEL SULLIVAN can be reached on (571)272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cab

/Rosalynd Keys/
Primary Examiner, Art Unit 1621